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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,968	06/22/2001	Thomas William Rademacher	1012E-000300	9989

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,968	RADEMACHER ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-46* is/are pending in the application.

4a) Of the above claim(s) *31-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-30 and 44-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. The amendment filed September 5, 2003 is acknowledged. Claim 22 was amended. Claims 44-46 were added.

2. Claims 22-46 are pending.

Claims 31-43, drawn to non-elected inventions, are withdrawn from consideration.

Claims 21-30 and 44-46 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Withdrawn:

Claim Objections

4. The objection to claim 22 because of an informality is withdrawn in view of the amendment.

5. The rejection of claim 26 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn upon further consideration. The antibodies used in claim 26 are antibodies that bind to IPG.

6. The rejection of claim 29 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not set forth in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of the amendment to the specification correcting the deposit information, and the inclusion of the statement that the antibodies will be made available in accordance with national laws.

7. The rejection of claims 22-25 under 35 U.S.C. 102(e) as being anticipated by Levitzki et al (U.S. Patent 5,932,580; issued Aug. 3, 1999; filed Dec. 1, 1997) as evidenced by Nazih-Sanderson et al (Biochemica et Biophysica Acta 1346: 45-60, 1997) is withdrawn in view of applicants' persuasive arguments that GPI-anchored proteins are not a source of IPG.

Claim Rejections Maintained:

8. The rejection of claims 22-25, 27 and 30 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons of record and applied to new claims 44-46.

The rejection of the claimed inventions because of a failure to adequately describe the structures of the antagonists to be used in the claimed methods is maintained. Applicants' arguments have been carefully considered but are unpersuasive. Applicants argue that the specification describes antibodies that bind to IPGs, and therefore describe IPG antagonists that

are substances capable of reducing the levels of IPGs by binding to IPGs. However, a description of antibodies is not adequate to describe the entire genus of possible substances that are capable of binding to IPGs. IPGs are biologically active molecules and presumably bind to cellular proteins or cell membrane proteins. The structures of these proteins have not been described in the prior art or in the specification. Therefore, the description of antibodies that bind to IPGs is not representative of the genus of all substances that are capable of binding to IPGs.

Additionally, the prior art teaches that IPGs and their GPI precursors have not been completely characterized structurally (see Varela-Nieto et al. Comp. Biochem. Physiol., 115B: 223-241, 1996, of record; page 224, 1st col. 2nd col). Therefore, the genus of substances that inhibit the release of IPGs, or are capable of reducing an effect of IPGs, or competitively bind to IPGs has not been adequately described structurally. Also, with respect to claim 30, it appears that the term "inhibitor of GPI-specific phospholipase type C" is not described because the prior art teaches that the specific phospholipase that is responsible for the generation of IPG from precursor GPI is unknown, as is the mechanism by which this enzyme is regulated (Varela-Nieto, supra; page 224, 1st col). Thus, applicant was not in possession of such inhibitors.

9. The rejection of claims 22-28 under 35 U.S.C. 103(a) as being unpatentable over Varela-Nieto et al (Varela-Nieto et al, Comp. Biochem. Physiol., 115B(2): 223-241, 1996) in view of Rademacher (WO 98/11116; published 19 March 1998) is maintained for the reasons of record and applied to claims 45 and 46.

Applicants' arguments have been carefully considered, but are unpersuasive. Applicant argues that the teachings of Varela-Nieto refer to an experiment using an IPG antibody that binds to an IPG derived from a GPI-anchored protein. However, Varela-Nieto also teaches that this antibody cross-reacts with IPG obtained by PtdIns-PLC hydrolysis of GPI purified from rat liver and chicken embryo, and uses this as an argument that IPG obtained from GPI-anchored proteins is similar in structure to IPG derived from free-GPI (see page 225, second col.). Furthermore, applicants argue that the Varela-Nieto teachings only apply to non-tumor cells. This argument is unpersuasive because Varela-Nieto teaches that IPG is involved in growth factor signaling, and growth factors are known to increase the growth of tumor cells. Therefore, this rejection is maintained.

Varela-Nieto teaches that anti-IPG antibodies inhibit proliferation of cochleovestibular ganglia cells that have been stimulated by BDNF or NT-3 (page 229, 2nd col., last paragraph). Varela-Nieto also teaches that IPG is involved in growth factor signaling (see page 232-233). Thus, the prior art teaches that IPGs interact with the second messenger system of many of the growth factor receptors that are targeted in tumor therapy regimens. WO 98/11116 is cited to demonstrate that specific antibodies that inhibit IPGs are available in the prior art. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have made a method for reducing tumor cell proliferation comprising administering antibodies that bind IPGs.

New Grounds of Rejection:

10. Claims 22-29, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable Rademacher (WO 98/11116; published 19 March 1998).

Rademacher teaches that an A-type IPG fraction is mitogenic to NIH-3T3 fibroblasts that have been transfected with the EGF receptor (page 26; page 21, line 37 to page 22, line 22). Reademacher teaches antibodies that bind to A-type IPGs (page 30-31), and specifically teaches one of the monoclonal antibodies, 2D1, of claim 29. In view of the fact that NIH-3T3 fibroblasts transfected with the EGF receptor are a model for tumor cell proliferation, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the monoclonal antibodies of Rademacher to make the claimed methods of reducing tumor cell proliferation.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
December 12, 2003